

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS washington, D.C. 20231 www.uspto.gov

DATE MAILED: 03/19/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,081	02/08/2001	Benjamin Oshlack	200.1133	7465
-	590 03/19/2002	OFE HE		·
485 SEVENTE	DAVIDSON & KAI	PEL, LLC /	EXAMINER	
485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018		(_ APR 3 o 2007	TRAN, SUSAN T	
		TANDART OF	ART UNIT	PAPER NUMBER
		PARMARK	1615	

Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No. 09/781,081 Applicant(s)

Examiner

Susan Tran

Art Unit 1615

Oshlack et al.



- The MAILING DATE of this communication appear	rs on the cover sheet with the correspondence address
Period for Reply	
A SHORTENED STATUTORY PERIOD FOR REPLY IS SI THE MAILING DATE OF THIS COMMUNICATION.	ET TO EXPIRE1 MONTH(S) FROM
after SIX (6) MONTHS from the mailing date of this commun	CFR 1.136 (a). In no event, however, may a reply be timely filed nication.
 If the period for reply specified above is less than thirty (30) da be considered timely. 	ys, a reply within the statutory minimum of thirty (30) days will
 If NO period for reply is specified above, the maximum statutor communication. 	y period will apply and will expire SIX (6) MONTHS from the mailing date of this
 Failure to reply within the set or extended period for reply will, Any reply received by the Office later than three months after that earned patent term adjustment. See 37 CFR 1.704(b). 	by statute, cause the application to become ABANDONED (35 U.S.C. § 133). the mailing date of this communication, even if timely filed, may reduce any
Status	
1) Responsive to communication(s) filed on	
2a) ☐ This action is FINAL. 2b) ☑ This a	oction is non-final.
3) Since this application is in condition for allowance closed in accordance with the practice under Ex.	e except for formal matters, prosecution as to the merits is parte Quayle, 1935 C.D. 11; 453 O.G. 213.
Disposition of Claims	
4) 💢 Claim(s) <u>1-105</u>	is/are pending in the application.
4a) Of the above, claim(s)	is/are withdrawn from consideration.
5) Claim(s)	is/are allowed.
6) Claim(s)	
7) Claim(s)	
8) 💢 Claims <u>1-105</u>	are subject to restriction and/or election requirement.
Application Papers	
9) \square The specification is objected to by the Examiner.	
10) The drawing(s) filed on is/a	re objected to by the Examiner.
11) The proposed drawing correction filed on	is: a)□ approved b)□ disapproved.
12) \square The oath or declaration is objected to by the Example 12.	niner.
Priority under 35 U.S.C. § 119	
13) Acknowledgement is made of a claim for foreign	priority under 35 U.S.C. § 119(a)-(d).
a) ☐ All b) ☐ Some* c) ☐ None of:	
1. Certified copies of the priority documents ha	ave been received.
2. Certified copies of the priority documents ha	ave been received in Application No
application from the international Bul	documents have been received in this National Stage reau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of t	
14) Acknowledgement is made of a claim for domest	ic priority under 35 U.S.C. § 119(e).
Attachment(s)	
5) Notice of References Cited (PTO-892)	18] Interview Summary (PTO-413) Paper No(s).
6) Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) Notice of Informal Patent Application (PTO-152)
7) Information Disclosure Statement(s) (PTO-1449) Paper No(s).	20) Other:

Art Unit: 1615

DETAILED ACTION

Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-59, and 61, drawn to an oral dosage form, classified in class 424,
 subclass 464+.
 - II. Claims 62-64, 75-80, 90-94 drawn to bi-layer dosage, classified in class 424, subclass 471.
 - III. Claims 65-68, 83-89, 95 drawn to three layers dosage form, classified in class 424, subclass 471.
 - IV. Claims 69-74, drawn to matrix dosage form, classified in class 424, subclass 484.
 - V. Claims 96-99, drawn to a composition, classified in class 424, subclass 451+.
 - VI. Claims 100-105, drawn to a composition and a method for treating pain, classified in class 424, subclass 451+.
- 2. This application contains claims directed to the following patentably distinct species of the claimed invention:
 - a. Layers dosage form
 - b. Multiparticulates, granules, beads, pellets
 - c. Coated multiparticulates
 - d. Matrix

Application/Control Number: 09/781,081 Page 3

Art Unit: 1615

e. Cellulose polymer

f. Acrylic polymer

g. Capsule

h. Tablet

I. Sustained release tablet

j. Sustained release capsule

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-9, 41, 54, 62, 63, 65, 69, 41, 73, 96, and 100 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Art Unit: 1615

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this case, the oral dosage form of Group I invention does not use the core as required in the invention of Group II.

Inventions Group I and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The oral dosage form of Group I invention does not require the third layer as the invention of Group III.

Inventions Group I and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this

Application/Control Number: 09/781,081

Art Unit: 1615

case, the composition of Group IV does not practice using the sequestered opioid antagonist required in the Group I invention.

Inventions Group I and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The composition of Group V does not require the layers as the invention of Group I.

Inventions Group I and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The composition of Group VI does not require the layers as the invention of Group I.

Inventions Group II and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The oral dosage form of Group II invention does not require the third layer as the invention of Group III.

Inventions Group II and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In this case, the composition of Group IV does not practice using the sequestered opioid antagonist required in the Group II invention

Application/Control Number: 09/781,081

Art Unit: 1615

Inventions Group II and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The composition of Group V does not require the layers as the invention of Group II.

Inventions Group II and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The composition of Group V does not require the layers as the invention of Group II.

Inventions Group III and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage of Group III invention does not require the use of hydrophobic material as the invention of Group IV.

Inventions Group III and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage form of Group V invention does not require the third layer as the invention of Group III.

Inventions Group III and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage form of Group VI invention does not require the third layer as the invention of Group III.

Inventions Group IV and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage of Group V invention does not require the use of hydrophobic material as the invention of Group IV.

Inventions Group IV and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage of Group VI invention does not require the use of hydrophobic material as the invention of Group IV.

Inventions Group V and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The dosage of Group VI invention requires the present of opioid agonist, while the invention of Group V does not.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VI, restriction for examination purposes as indicated is proper.

Application/Control Number: 09/781,081

Art Unit: 1615

Applicant is advised that the reply to this requirement to be complete must include an

election of the invention to be examined even though the requirement be traversed (37

CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the

fee required under 37 CFR 1.17(I).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can

normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the

organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY) CENTER 1600

Page 8